

Patent Application
Attorney Docket No. 5950-01-CA

REMARKS/ARGUMENTS

Claims 7, 8, 9, and 10 have been cancelled. Claim 1 has been amended to remove verbiage and to replace the phrase "consisting essentially of" with the phrase "consisting of". Thus, claims 1, 5, and 6 are pending in the present application.

CLAIM REJECTIONS - 35 USC § 112, FIRST PARAGRAPH

The Examiner rejected claims 1 and 5-10 under 35 USC § 112, first paragraph, as failing to comply with the written description requirement. The Examiner alleges that the limitation "consisting essentially of" lacks antecedence in the specification. According to the Examiner, Applicant's disclosure fails to teach a method comprising solely the step of administering cholesterol lowering agents. The Examiner concludes that for purposes of examination "consisting essentially of" is assumed to include some dietary modifications.

In response to the Examiner's rejection and as indicated above, Applicant has amended claim 1, so that the claim incorporates the transitional phrase "consisting of" instead of "consisting essentially of". Since the basis for the 35 USC § 112, first paragraph has been rendered moot by the amendment, Applicant respectfully requests that the rejection of claims 1, 5, and 6 under 35 USC § 112, first paragraph, be withdrawn.

CLAIM REJECTIONS - 35 USC § 103

In paragraphs 5, 6, and 7 of the Office Action, the Examiner rejected claims 1 and 5-10 as being obvious in view of several publications. The substance of paragraphs 6 and 7 of the Office Action are not addressed herein because they relate to now-cancelled claims 7, 8, 9, and 10. In paragraph 5, the Examiner alleges that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method disclosed by Seed (U.S. Patent No. 5,861,399) in view of Bocan (WO 97/16184). This rejection is respectfully traversed.

To establish a prima facie case of obviousness, three criteria must be met. First, there must be some suggestion or motivation in the reference or in the knowledge generally available to one of ordinary skill in the art to modify the reference teaching. Second, there must be a reasonable expectation of success. Finally, the reference must teach or suggest all the claim limitations.

As amended, the present claims are directed toward a method for preventing or delaying catheter-based revascularization in patients suffering from coronary artery disease and in need of

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such treatment consisting of administering atorvastatin in an amount effective to cause an aggressive lowering of LDL cholesterol. The Applicant emphasizes that he is the first to show that administration of high doses of a cholesterol lowering drug such as atorvastatin reduces the incidence of an adverse cardiac event from 21% to 13%, thereby decreasing the need for revascularization (see present specification at page 25, lines 5-24).

Seed discloses a method for reducing coronary artery stenosis by at least 20 %. The method involves the administration of a cholesterol lowering therapeutic combined with dietary restrictions (col. 2, lines 62-65). Seed does not disclose atorvastatin in the method, let alone a method for preventing or delaying catheter-based revascularization in patients suffering from coronary artery disease using atorvastatin alone, as claimed by the Applicant.

Bocan discloses a method and pharmaceutical composition for regulating lipid concentration (Title). The composition comprises the combination of an ACAT inhibitor with an HMG-CoA reductase inhibitor, including atorvastatin. According to Bocan, the combination of ACAT inhibitors and HMG-CoA reductase inhibitors (i) reduces apo B-containing lipoprotein levels to a greater extent than either inhibitor alone; (ii) that a normalization of plasma lipoprotein profile is achieved; and (iii) that the histologic character of atherosclerotic lesions is less complicated when the combination is used. In contrast to Applicant's disclosure, however, Bocan does not disclose that catheter-based revascularization in patients suffering from coronary artery disease can be prevented or delayed by administering a cholesterol lowering agent in an amount effective to cause an aggressive lowering of LDL cholesterol.

Taken alone or in combination, Seed and Bocan fail to disclose the sole use of atorvastatin to prevent or delay catheter-based revascularization in patients suffering from coronary artery disease. In short, the references fail to teach all of the claim limitations recited in Applicant's amended claim 1. As a result, the third criterion of the *prima facie* obviousness determination has not been met.

Moreover, the skilled artisan would not read Seed taken alone or in combination with Bocan as suggesting or motivating the use of atorvastatin alone to prevent or delay catheter-based revascularization in patients suffering from coronary artery disease. Therefore, the first criterion of the *prima facie* obviousness determination has not been met. Indeed, if combined, Seed and Bocan would provide the motivation to employ a statin and ACAT inhibitor together with dietary restrictions, *not* a statin alone. In that respect, the references *teach away* from the Applicant's invention as recited in the amended claims.

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Finally, since Seed and Bocan effectively teach away from the claimed invention, by suggesting the use of a statin with an ACAT inhibitor together with dietary restrictions, the skilled artisan could not reasonably expect success in pursuing an invention that consists of the use of atorvastatin alone to prevent or delay catheter-based revascularization in patients suffering from coronary artery disease. As a result, the second criterion of the *prima facie* obviousness determination has not been met.

Applicants submit that the claims, as currently amended, are non-obvious and thus patentable over Seed and Bocan taken separately or in combination, and respectfully request that all rejections of the claims under 35 USC § 103 be withdrawn. Reconsideration of this application, as amended, and its allowance is therefore respectfully requested.

Respectfully submitted,

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